



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Amprion, Inc. located in Houston Texas, USA, to practice the inventions embodied in the following Patents and Patent Applications, each entitled “Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein”:

1. US provisional Application 60/961,364 filed July 20, 2007 [HHS Ref. No. E-109-2007/0-US-01]
2. PCT/US2008/070656, filed July 21, 2008; [HHS Ref. No E-109-2007/1-PCT-01]
3. EPC application No 08796382.3 filed July 21, 2008 [HHS Ref. No E-109-2007/1-EP-03]
4. US Application No. 12/177,012, filed July 21, 2008 and issued as US patent 8,216,788 on July 10, 2012 [HHS Ref. No E-109-2007/1-US-02];
5. US Application No. 13/489,321, filed June 5, 2012 [E-109-2007/1-US-04];
6. US Application No. 14/263,703, filed April 28, 2014 [E-109-2007/1-US-011]

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive licensed territory may be worldwide and the field of use may be limited to in vitro diagnostics of prion-associated diseases requiring FDA premarket approval, or the equivalent thereof outside of the United States, and USDA licensed veterinary diagnostics, or the equivalents thereof outside of the United States.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before 11:59 pm Eastern Time on [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patents and applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: fennea@mail.nih.gov; Telephone: 424-297-0336; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The invention relates to methods and compositions for the detection of infectious prions and diagnosis of prion related diseases. Currently, available tests for disease-causing prions are incapable of detecting low concentrations and must be confirmed post-mortem. This technology enables rapid and economical detection of sub-lethal

concentrations of prions by using recombinant protein (rPrP-sen) as a marker. A seeded sample polymerizes rPrP-sen, which is detected as an amplified indicator of prions in the sample. This assay does not require multiple amplification cycles unless a higher degree of sensitivity is required. This technology potentially may be combined with additional prion-detection technologies to further improve the sensitivity of the assay.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Any additional applications for a license in the field of use, filed in response to this notice, will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 10, 2014

Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health

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